

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

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| Applicant's or agent's file reference PF-0625 PCT | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) | |
| International application No. PCT/US99/25021 | International filing date (<i>day/month/year</i>) 27 OCTOBER 1999 | Priority date (<i>day/month/year</i>) 27 OCTOBER 1998 |
| International Patent Classification (IPC) or national classification and IPC Please See Supplemental Sheet. | | |
| Applicant INCYTE PHARMACEUTICALS, INC. | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets.
- ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
- These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

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| Date of submission of the demand 17 MAY 2000 | Date of completion of this report 14 JUNE 2001 |
| Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 | Authorized officer TERRY J. DEY TEKCHAND SAIDHA PARALEGAL SPECIALIST TECHNOLOGY CENTER 1600 |
| Facsimile No. (703) 305-3230 | Telephone No. (703) 308-0196 |

I. Basis of the report**1. With regard to the elements of the international application:***

- ☒ the international application as originally filed
- ☒ the description:
pages 1-59 , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____
- ☒ the claims:
pages 60-61 , as originally filed
pages NONE , as amended (together with any statement) under Article 19
pages NONE , filed with the demand
pages NONE , filed with the letter of _____
- ☒ the drawings:
pages 1-6 , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____
- ☒ the sequence listing part of the description:
pages NONE , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

- ☒ the description, pages NONE
- ☒ the claims, Nos. NONE
- ☒ the drawings, sheets/fig NONE

5. ☐ This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

*** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

***Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application.

☒ claims Nos. 17-18 AND 20

because:

☐ the said international application, or the said claim Nos. _ relate to the following subject matter which does not require international preliminary examination (*specify*).

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _ are so unclear that no meaningful opinion could be formed (*specify*).

☐ the claims, or said claims Nos. _ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 17-18 AND 20.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. statement**

| | | |
|-------------------------------|-------------------------|-----|
| Novelty (N) | Claims <u>14-16, 19</u> | YES |
| | Claims <u>1-13</u> | NO |
| Inventive Step (IS) | Claims <u>NONE</u> | YES |
| | Claims <u>1-16, 19</u> | NO |
| Industrial Applicability (IA) | Claims <u>1-16, 19</u> | YES |
| | Claims <u>NONE</u> | NO |

2. citations and explanations (Rule 70.7)

Claims 1-13 lack novelty under PCT Article 33(2) as being anticipated by accession number AA762051 (Marra et al. : The WashU-HHMI Mouse EST Project, see search report). Claims recite the phrase "or a fragment thereof" referring to isolated DNA or RNA or the encoded polypeptide. Claim also recites "a sequence which is complementary to the DNA, 90% sequence homology or stringent hybridization conditions...". There is no limitation present in the claims which would restrict the size of the claimed polynucleotide/polypeptide fragment(s). Di- and tri- nucleotides/amino acid residues are well known in the art of molecular biology and chemistry and are encompassed by the scope of these claims. However, the cited art display more than di or tri nucleotides/amino acid residues. Therefore, the claims are anticipated by the reference.

Claims 14-16 and 19 lack an inventive step under PCT Article 33(3) as being obvious over accession number AA762051 in view of US 5279957. US Patent 5279957 teaches an analogous phospholipase and recombinant method of producing the polypeptide. With the fragments of the specific sequences disclosed in the accession number AA762051 or any sequence, it would have been obvious for a person of ordinary skill to use the suitable vector, host cells and method of producing the protein following the detailed guidance provided in US patent 5379957.

Claims 1-16 and 19 have industrial applicability under PCT Article 33(4), because the subject matter claimed can be made or used in industry.

Applicants response filed 5.10.01 to the written opinion is acknowledged. It is noted that Applicants fully traverse Examiner's objections and elect to address these and other objections in the national stage applications to be filed.

----- NEW CITATIONS -----
NONE

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

CLASSIFICATION:

The International Patent Classification (IPC) and/or the National classification are as listed below:

IPC(7): C12N 9/20, 1/20, 15/00; C07H 21/04; A61K 38/00; C07K 1/00, 16/00 and US Cl.: 435/198, 252.3, 320.1; 536/23.2; 530/300, 350, 387.1; 424/94.6